REMARKS

Claims 1-8 are pending and presently under rejection. Withdrawal and reconsideration of the rejections are respectfully requested.

Rejections under 35 USC 112

The Examiner has rejected claims 1-2 under 35 USC 112 first paragraph as containing subject matter which was not adequately described in the specification. The Examiner alleges that while a method of treating a proliferative disease is adequately described on pages 24 and 25 of the specification, that other "conditions susceptible to treatment with an ALK inhibiting agent" are not adequately described.

The compounds of formula I have been described in the specification as those which, "possess valuable pharmacologically useful properties. In particular the pyrimidine derivatives used according to the present invention exhibit specific inhibitory activities that are of pharmacological interest. They are effective especially as protein tyrosine kinase inhibitors; they exhibit, for example, powerful inhibition of the tyrosine kinase activity of anaplastic lymphoma kinase (ALK) and the fusion protein of NPM-ALK." (See page 1, second paragraph, lines 2-6 of the specification).

This description of the compounds of the claimed method as ALK inhibitors is further supported by the accompanying data on pages 30-31 of the specification. Because the specification describes the pharmacologically useful properties of ALK inhibition, and further demonstrates ALK inhibition, there is support in the specification for treatment of a condition susceptible to treatment with an ALK inhibiting agent. The rejection is respectfully traversed.

The Examiner has also rejected claims 1-8 as not being enabling for the prevention of conditions susceptible to treatment with an ALK inhibiting agent. The claims have been amended to remove prevention as such. Withdrawal and reconsideration of the rejections are requested.

The Examiner has also rejected claims 1-8 as not being enabled for treating conditions beyond non-Hodgkin's lymphoma. It is well established however, that if *in vitro* tests correlate to a claimed method of invention, it constitutes a working example sufficient to provide enablement of the claims. See, e.g., MPEP 2164.02. This is particularly the case in

instances where the state of the art recognizes such a correlation. In the present case, the compounds of the invention were shown to potently inhibit activity of ALK tyrosine kinase, as demonstrated on pages 30-31 of the specification. Withdrawal and reconsideration of the rejection are respectfully requested.

Rejection under 35 USC 102

The Examiner has rejected the claims under 35 USC 102(e) as being anticipated by commonly owned Baenteli et al (WO 03/078404). The rejection is respectfully traversed.

For a rejection to be proper under 35 USC 102, each and every claimed element must be present in the anticipating reference. The rejection is improper in this case because Baenteli does not disclose "a method of treating a condition susceptible to treatment with an ALK inhibiting agent which comprised inhibiting ALK or a gene fusion thereof with a compound of formula I." The Examiner acknowledges that Baenteli does not disclose or teach the ALK inhibitory effect of the compounds, but indicates that, "this activity is a property of the compound and is necessarily present." (Office Action, page 6, first full paragraph, lines 6-8). The Examiner, in other words, is claiming the property to be inherent in the prior art.

In order to establish inherency however, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill in the art. See MPEP 2112.IV. In the present case, the compounds of Baenteli were disclosed as being useful in treating diseases or conditions in which ZAP-70, FAK, or Syk tyrosine inhibition activity is implicated. The compounds are identical to those of the presently claimed method of treating diseases associated with ALK inhibition.

One of skill in the art would not recognize the compounds of Baentelli as being useful in treating or preventing a condition susceptible to treatment with an ALK inhibiting agent. The Examiner has further offered no suggestion that one of skill in the art would recognize the utility of Baentelli's compounds in the presently claimed method. Mere overlap of diseases listed does not constitute a proper anticipation of a new method of treatment via a new target. The rejection is therefore improper, and should be withdrawn.

Should the Examiner have any questions, please contact the undersigned attorney.

Respectfully submitted,

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